

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2004N-0330]

Food and Drug Administration

*Dockets*  
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**Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committees:* Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee.

*General Function of the Committees:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 13, 2004, from 8 a.m. to 6:30 p.m. and on September 14, 2004, from 8 a.m. to 5 p.m.

*Addresses:* Electronic comments should be submitted to <http://www.fda.gov/oc/dockets/ecomments>. Select "2004N-0330—Suicidality in Clinical Trials for Antidepressant Drugs in Pediatric Patients" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments received by August 23, 2004, will be provided to the committee before the

meeting. Comments received after August 23, 2004, will be reviewed by FDA's decision makers.

*Location:* Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person:* Anuja Patel, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [patelA@cder.fda.gov](mailto:patelA@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

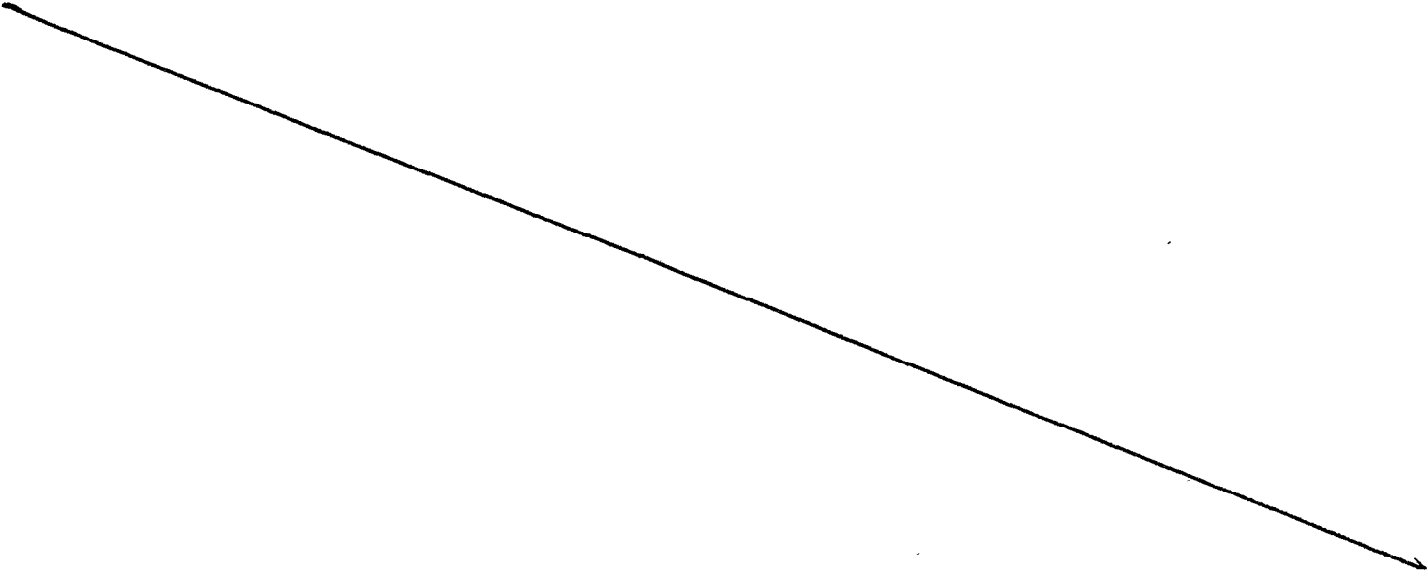
*Agenda:* The Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee will discuss reports of the occurrence of suicidality (both suicidal ideation and suicide attempts) in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder and other psychiatric disorders. Preliminary risk data based on the classification of these adverse event reports by the pharmaceutical sponsors of these products were presented at the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee held on February 2, 2004. Since that meeting, experts in pediatric suicidality, assembled by Columbia University, have independently classified these reported events, and FDA has conducted an analysis of these data. On September 13 and 14, 2004, the committees will consider the results of FDA's analysis of these independently classified events and will consider what further regulatory action may be needed with regard to the clinical use of these

products in pediatric patients. The committees will also consider further research needs to address questions on this topic.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the Division of Dockets Management before August 23, 2004, as previously stated (see *Addresses*). Oral presentations from the public will be scheduled between approximately 2 p.m. to 6 p.m. on September 13, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 27, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

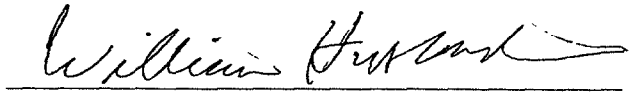
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Anuja Patel at 301-827-7001, at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated: JUL 29 2004

July 29, 2004.



William K. Hubbard,  
Associate Commissioner for Policy and Planning

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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